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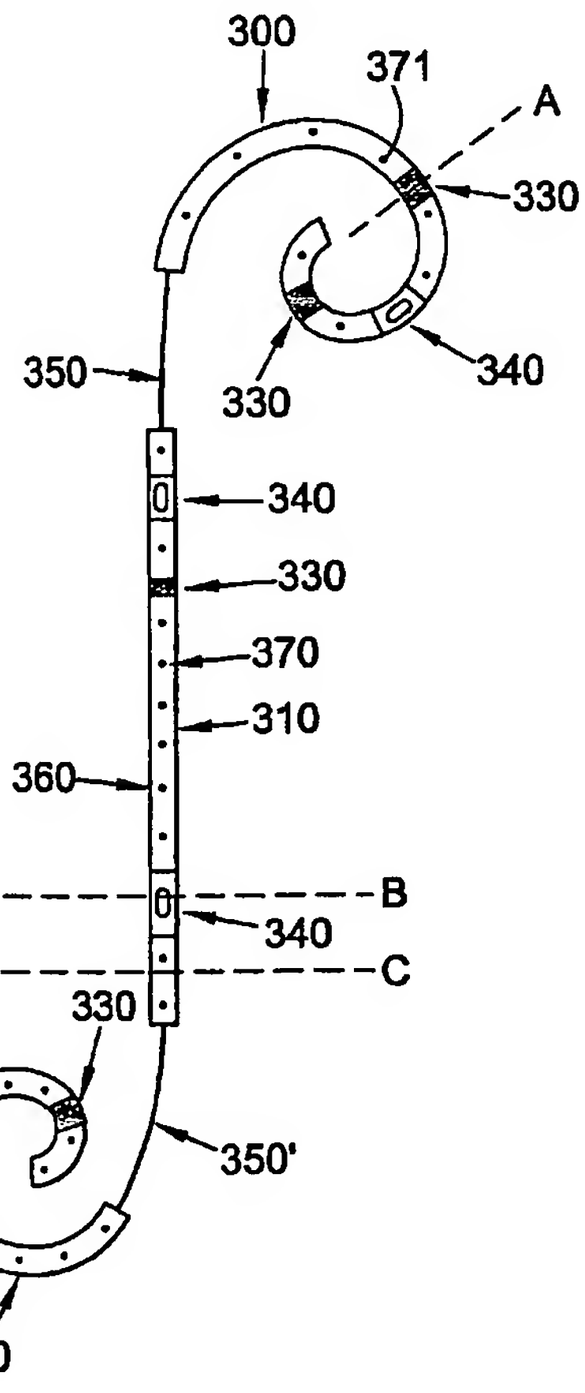

(57) Abstract: The present invention provides a ureteric stent having a proximal end and a distal end, said stent comprising: (i) a proximal retention end portion (300) positioned at the proximal end of the stent, said proximal retention end portion being adapted to retain said proximal portion in the renal pelvis of the patient; (ii) at least one strand portion (350) wherein said strand portion(s) has an outside diameter significantly less than the outside diameter of the proximal retention end portion; characterised in that the strand portions) are located along the length of the stent such that, in use, the strand portion(s) are located across the pelviureteric junction and/or the vesicoureteric junction of the patient.

WO 2005/096991 A1

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URETERIC STENTS

Field of the invention

This application relates to ureteric stents.

Background to the invention

Ureteric stents are used to assist drainage of urine from the kidney to the bladder. They are commonly used in the presence of obstruction or injury to the ureter, or post surgical intervention.

Ureteric stents are usually tubular structures, with one end positioned in the kidney and the other in the bladder. These ends may be coiled or J-shaped. The aim of this shaping is to prevent migration of the stent up or down the ureter.

Ureteric stents can cause a variety of severe symptoms including urgency, frequency, bladder pain and kidney pain on micturition. These symptoms are at least in part due to the fact that the stent disrupts the physiological anti reflux mechanism. Prior to reaching the bladder a one to two centimetre section of the distal ureter passes through the muscular bladder wall. This acts like a one way valve allowing urine to pass from the kidney to the bladder, but not vice versa. At the pelviureteric junction the muscular wall of the ureter can also act to a lesser extent like a sphincter. Conventional ureteric stents keep both the vesicoureteric and pelviureteric junctions open. This is an unphysiological situation and allows reflux of urine from the bladder to the kidney.

Figure 1 shows a schematic drawing of the urinary tract with a typical prior art ureteric stent in situ. These stents are typically 4-8 mm in circumference and have holes along their length.

Obstruction to the urinary system can be caused by a condition known as pelviureteric junction (PUJ) obstruction. The underlying cause for this obstruction is poorly understood. It is commonly diagnosed with the use of a nuclear medicine scan, however this provides relatively qualitative data on the severity of the

used. This test involves inserting a needle through the skin into the collecting system of the kidney. The collecting system is then perfused at a rate of 10mls per minute and any resulting pressure rise recorded by a transducer connected to the needle (figure 2). The Whitaker test is reserved for complex cases because of its invasive nature and the fact that there is a small risk of haemorrhage, this occasionally requires surgical removal of the kidney to control it. However the Whitaker test remains the only method available to quantitatively measure the intrarenal pressures and hence the severity of the obstruction.

Once diagnosed, PUJ obstruction is managed by either endoscopic, percutaneous, laparoscopic or open surgical repair. Follow up to ensure a successful outcome is often with a repeat nuclear medicine scan or an intravenous urogram. However both of these provide a relatively qualitative rather than quantitative assessment of the operative result. Therefore it has been difficult to give absolute differences in outcome between different surgical methods in trials to compare different methods of treating PUJ obstruction.

Another condition which provides a difficult diagnostic and therapeutic problem for clinicians is the loin pain haematuria syndrome. In this condition patients present with loin pain and haematuria for which no underlying cause can be found with conventional modalities of urological investigation. Treatment is symptomatic but in the most severe cases leads to surgical removal of the kidney. In some instances stenting has been tried to alleviate the pain, but conventional ureteric stents do not allow any detailed information about the function of the renal pelvis, ureter or bladder to be obtained.

A wide variety of designs for ureteric stents are known. One such design is described in US 6,656,146 (Clayman et al.). This represents the closest prior art known to the applicant and the entire text of US 6,656,146 is hereby imported by reference and is intended to form an integral part of this description. US 6,656,146 describes a ureteric stent having a flexible tail made up of multiple filaments. This so-called tail lies, in use, only in the lower part of the ureter and in the bladder, unlike the stent of the present invention where a single strand or filament may be used to connect various tubular portions of the device, especially in the region of the pelviureteric junction.

Summary of the invention

This invention provides, in one embodiment, an indwelling ureteric catheter comprised of a flexible tube with an upper end section, a substantially straight middle section and a lower end section. These three sections may run in continuity or may be connected by at least one thin flexible strand. The proximal or upper end section is designed and may be adapted to be sited in the renal pelvis. The strands connecting this section to the middle section cross the pelviureteric junction causing minimal disruption to the normal physiology of the pelviureteric junction. The lower or distal end section is located in the bladder. The strands connecting this section to the middle section cross the vesicoureteric junction causing minimal disruption to the normal physiology of the vesicoureteric junction. A central lumen runs along the upper, middle and lower end sections.

In the present disclosure the term "distal" refers to the end of the stent which, in use, is closest to the outside of the body. Generally this is the end nearest the patient's bladder. Similarly, the term "proximal" refers to the end of the stent which is higher up the system and which, in use, is furthest into the body. Generally this is the end in the kidney.

The upper section is preferable coiled. The lower end section may be coiled in the bladder, or may be bought out straight either along the urethra, or for example through the bladder suprapubically.

The catheter contains a number of electrodes and/or pressure sensors or pressure transducers which can be present in any of the 3 main sections. These electrodes/transducers may be connected electrically via the strands connecting the upper and lower ends to the middle section. In the upper, middle or lower sections of the stent the cabling for the electrodes/transducers may run along the central lumen of the stent. In another embodiment of the stent this cabling may run in specific channels/tunnels in the wall of the stent. The electrodes allow peristalsis to be stimulated for diagnostic or therapeutic applications. The pressure sensors/transducers allow the intra luminal pressure to be measured. The strands crossing the pelviureteric junction and the vesicoureteric junction do not disrupt the normal physiological state of these areas or obstruct the outflow, so the pressures

measured reflect those that would be measured in a Whitaker test, but without the need to place a nephrostomy tube into the kidney.

The catheter may also contain a battery supply and a telemetry system to transmit the recorded signals to the outside. Alternatively if the lower end is substantially straight and brought our transurethrally then the power supply can be external, and the recordings from the transducers conducted externally rather than transmitted via telemetry.

Conventional ureteric stents partially obstruct the drainage of the kidney and have therefore not been used in the assessment of upper urinary tract obstruction. The use of a stent where fine strands that cross the pelviureteric junction allows this area to be studied, unobstructed by the stent. In a similar manner the vesicoureteric junction can be studied, unobstructed by the stent.

Therefore, according to a first aspect of the present invention there is provided a ureteric stent having a proximal end and a distal end, said stent comprising:

(i) a proximal retention end portion positioned at the proximal end of the stent, said proximal retention end portion being adapted to retain said proximal portion in the renal pelvis of the patient;

(ii) at least one strand portion wherein said strand portion(s) has an outside diameter significantly less than the outside diameter of the distal retention end portion;

characterised in that the strand portion(s) are located along the length of the stent such that, in use, the strand portion(s) are located across the pelviureteric junction and/or the vesicoureteric junction of the patient.

Providing strand sections with a very small diameter causes minimum physiological disturbance to the sphincter muscles in the urinary tract.

Preferably the proximal retention end portion takes the form of a pre-formed coil. Coils are a well known method for keeping this type of stent in place but many other methods are possible.

Preferably the proximal retention end may be formed from a tubular material having a hollow lumen. This form of construction is similar to known ureteric stents.

Preferably the distal end of said stent comprises a distal end retention portion adapted to retain said distal end in bladder of the patient.

Preferably the distal end retention portion takes the form of a pre-formed coil. Again, this is only one form of retention means which can be used. It is intended that this invention should include any suitable retention means for this purpose, both known and those yet to be discovered.

Preferably distal retention end portion is formed from a tubular material having a hollow lumen.

Preferably the stent incorporates an intermediate portion, intermediate between the distal end retention portion, if present, and the proximal end retention portion, said intermediate portion being connected to adjacent portions by strands. This arrangement ensures that strands or filaments are present whenever the device passes through a sphincter muscle.

Preferably said intermediate portion is formed from a tubular material having a hollow lumen.

In a particularly preferred embodiment the stent further comprises one or more pressure transducers. Including one or more pressure transducers means that the pressure within the urinary tract can be measured at various points on a continuous or intermittent basis.

Preferably one or more pressure transducers are positioned in one or more of the distal portion, the intermediate portion and/or the proximal portion of the stent.

Preferably signals from the pressure transducer(s) are transmitted from the stent via the strand portion(s).

In a further particularly preferred embodiment said stent further comprises stimulating electrodes.

Preferably one or more electrodes are positioned in one or more of the distal portion, intermediate portion and/or the proximal portion of the stent. This enables the physician to stimulate various regions of the urinary tract as required.

In one embodiment a stimulating electrode is positioned on the stent and a return electrode is positioned elsewhere on the patent's body.

In a further embodiment a stimulating electrode and a return electrode are both positioned on the stent.

Preferably a strand portion is secured to the adjacent portion of larger diameter by use of securing means. A wide variety of strand securing means are envisaged, as would be determined by the materials specialist.

Preferably said securing means comprises one or more knots tied in the strand. Knots are easy to form and can be concealed within the tubular portion of the section to which the strand is attached.

In a particularly preferred embodiment the strand portion takes the form of a loop and is knotted to itself through the adjacent portion. Once again, the knot can be concealed and accommodated within the tubular part of the stent.

In an alternative embodiment the securing means comprises heat sealing or crimping.

In an alternative embodiment the stent comprises a proximal retention portion and a strand portion, the strand portion being dimensioned such that it may be brought directly to the outside of the body along the ureter, through the bladder and along the urethra.

In a further alternative embodiment the proximal retention end portion is adapted to retain said proximal portion in the bladder of the patent rather than in the renal pelvis. In this version the kidney is not affected and the stent only goes a far as the bladder. In all other respects the construction remains the same, including provision of pressure transducer(s) and electrical stimulating electrodes.

In summary, in its broadest sense, the invention comprises a ureteric stent which has a proximal retention portion, which is typically a coiled region, and a strand portion which extends, in use, through the pelviureteric function and/or through the vesicoureteric junction. There may also be a distal retention portion to retain the device in the bladder. At strategic locations along the stent electrical stimulation electrodes and pressure sensors are located. The stent may comprise one or more tubular portions connected by flexible strands or, if required, substantially the entire length of the stent may be formed from a strand of material providing the other features described above are present, including at least one proximal retention portion.

The technology to provide miniature pressure sensors of less than 1mm outside diameter is already known. For example, such sensors are available from Radi Medical Systems Inc. of Uppsala, Sweden.

The present invention also extends to include methods of performing a modified Whitaker diagnostic test using a stent according to the present invention, and to methods of treatment and diagnostics of animal or human patients using such a device.

It will also be appreciated that this invention includes methods of manufacturing stents according to the present invention. Certain suitable manufacturing methods are described in US 6,656,146, the text of which is incorporated herein by reference.

Brief description of the drawings

The invention will now be described by way of example only with reference to the accompanying drawings wherein:-

Fig. 1 is a schematic drawing of the human urinary tract with a prior art stent in-situ;

Fig. 2 depicts a schematic drawing of the human urinary tract during the Whitaker test;

Fig. 3 shows one preferred embodiment of the invention;

Fig. 4 shows diagrammatic cross sectional drawings from cross sections A, B and C as shown in Figure 3;

Fig. 5 shows a further preferred embodiment of the present invention;

Fig. 6 shows a further preferred embodiment of the present invention comprising a coiled region and a strand portion only.

Description of the preferred embodiments

In figure 1, a prior art ureteric stent 100 is depicted in situ with an upper or distal end 110 in the renal pelvis, a middle or intermediate section 120 in the ureter and a tail or proximal end 130 in the bladder 140. The stent crosses and keeps open the pelviureteric junction 150 and the vesicoureteric junction 160. As a consequence this allows reflux of urine from the bladder to the kidney, and causes partial obstruction to the outflow from the kidney. The distal end of the stent 130, may be either curled in the bladder with attached strings 170, which pass along the urethra 180 and allow the stent to be pulled out when desired, or it may be straight and pass along the urethra to the outside of the body. The right ureteric orifice 190, which is unstented is also shown.

In the examples described in figure 1 and later in figures 3, 5 and 6, the curled regions of the stent serve as a retention means to retain the stent in either the renal pelvis or bladder of the patient, or both. A coil is just one form of suitable retention means which could be used, but is not the only form which could be employed. For example, a flared portion could be used as described in US 2004/0249470 (Willet Whitmore III), the entire text of which is hereby incorporated by reference, and is intended to form an integral part of this disclosure.

In figure 2, a schematic diagram of the set up for the Whitaker test is depicted. A cannula 200 has been inserted into the kidney. The cannula 200 is connected to a fluid reservoir 210 which perfuses the kidney at a rate of 10mls per minute. The cannula is also connected to a pressure transducer/recorder system 220.

In figure 3 one of the preferred embodiments of the present invention is depicted. It shows an upper end 300, a middle section 310 and a lower end 320. In this

embodiment the stent comprises a proximal retention end portion positioned at the proximal end of the stent, the proximal retention end portion being adapted to retain the proximal end of the stent in the renal pelvis of the patient. The proximal retention end portion is then connected to a strand portion which in turn is connected to an intermediate portion 310. This in turn is connected to a further strand portion 350 and this strand portion is in turn attached to a distal end retention portion 320 adapted to retain the distal end of the stent in the bladder of the patient. It will be appreciated that the strand portions are so located along the length of the stent such that, in use, the strand portions are located across the pelviureteric junction and the vesicoureteric junction of the patient.

The tubular regions may incorporate several openings in the wall of each section, shown as 370 and 371 in Figure 3. These openings may be arranged in various geometries (e.g. axial, circumferential, spiral). The entirety of the tubular portions of the stent may incorporate these openings if required.

The distal, proximal and intermediate portions, as shown in figure 3, may be formed from suitable material as selected by the materials specialist. These include any conventional stent material which is typically a biocompatible polymeric plastics material, a coated plastic, or silicone, with a tubular cross-section and a hollow lumen. Typical dimensions for these tubular sections are 4 to 10 French which approximates to an outside diameter in the region of 1mm to 3mm. Such measurements are approximate but give an indication of the general scale of the cross-section of such stents.

The strand portion is constructed from any suitable filament or fibre material as selected by the materials specialist. An important feature of this invention is that the strand portion has an outside diameter which is significantly less than the portions of the stent described above. Typical outside diameters for the strand portion are less than 1mm and preferably 0.1mm to 0.7mm and more preferably 0.2mm to 0.6mm. The strands may be formed from a plastics material monofilament such as nylon or other biocompatible polymers. Alternatively, a multifilament thread or wire could be used. Where it is required to conduct electrical signals from pressure sensors or electrical impulses to electrodes, then a conducting core may be included in these strands. Typically such a conducting core would be made from a metal such as copper or silver.

The upper end may contain at least one electrode preferably a ring electrode in type 330. There may be more than one electrode present. In the situation where there are multiple electrodes, one could be used as the cathode and one the anode, alternatively one or more could be used as stimulating electrodes with the return electrode positioned somewhere else on the patients body. Miniature electrodes of this type are known *per se*, and their construction will be specified by the appropriate materials specialist. Furthermore, electrical controllers to stimulate the amount, frequency and pulse length of such electrical stimulation are also well known.

In a further aspect of a preferred embodiment pressure transducers 340 are located at various locations in the upper middle and lower sections of the stent. Although shown as present in all sections of the stent in another embodiment of the stent pressure transducers may only be present in one section if desired. In addition at least one flexible strand 350 is present between the upper and middle sections and between the middle and lower sections. In one preferred embodiment this strand carries wires which allow conduction of the signal from the pressure transducer, or stimulus to pass to the electrodes. The stent may also contain one or more holes 360 along its length.

Miniature pressure transducers of a suitable size and pressure measuring range are available from a number of suppliers. One such supplier is Gaeltec Limited of Dunvegan, Isle of Skye, Scotland, IV55 8GU. A typical pressure measuring range is from 0 to 400 mm H_2O.

In figure 4, cross sections of the invention are shown at the levels of A,B and C as shown in figure 3. Figure 4A shows a cross section of a ring electrode 400, this may be hollow in the centre as shown in the figure or may be solid. Figure 4B shows a cross section of a pressure transducer 410 and figure 4C shows the channels 420 that wires may run along within the stent wall. Alternatively the wires 430 may run along the central lumen of the catheter. When the centre of the stent is hollow, a guide wire can be passed along it, allowing the stent to be accurately positioned in the urinary tract, so that the strands between the upper and middle sections cross the pelviureteric junction and the strands between the middle and lower section cross the vesicoureteric junction. When the lumen through the stent is obscured by

electrical/signal conducting wires and/or a strand or strands or strand securing means, or the lumen is not large enough to pass a guide wire, then the stent may be sited with the aid of a ureteric sheath.

In figure 5 a further embodiment of the present invention is shown. The upper end 500 is connected to the middle 510 and lower 520 sections by at least one thin flexible strand 550. This strand or these strands may contain electrical wires for conducting the signals to/from the electrodes 530 and pressure transducers 540. The wires pass along the centre of the stent. In the embodiment illustrated in figure 5, the middle 510 and lower 520 end sections are continuous and would be brought to the outside of the body, preferably along the urethra. Alternatively the upper 500 and middle 510 sections may be continuous and the lower end 520 section connected to the middle section via a fine strand or filament.

In a further embodiment of the present invention, the strands may be of variable length. For example in Figure 5 the strand 550 may run from the renal pelvis to the bladder or be even longer and run along the urethra to the outside of the body. In this arrangement the strand(s) essentially replace the previous middle and lower sections. In yet another embodiment of the invention the strand(s) may also replace the middle section, for example in Figure 3 the middle section 310 would be replaced by a continuous strand connecting the upper end 300 to the lower end 320. Replacing the flexible tube sections of the stent with strand(s) has the advantage of minimising the obstruction to the urinary system. In addition to this, the ends of the stent whether they be facing each other in between sections or at either end of the stent should be tapered. This has the advantage of reducing trauma to the urinary system during insertion and withdrawal of the stent. In yet another embodiment of the invention radio opaque markers may be placed along any of the sections of the stent to allow accurate placement of the stent *in vivo*.

The strand is secured to the tubular portion of the stent using a strand securing means. The strand when single may preferably be knotted with the knot on the inside of the lumen and the strand passing through a small hole in the wall of the tube to the outside of the stent. The other end of the strand may be secured in a similar fashion. Alternatively both ends of the strand may be secured to the stent by another method such as heat sealing or crimping. In this way multiple single strands may be used.

In yet another embodiment of the invention the strand may be looped or doubled back on itself. The two ends of the single strand can then be tied together forming a loop. Preferably the knot would be positioned so that it is inside the lumen of the stent. Referring to figure 3, a single strand 350 is shown. When this is looped the strand would pass from the inside of the curled part of the stent 300, to the outside. It would then pass from the outside of the straight part of the stent 310 to the inside. The two ends which are both inside can be knotted. The strand whether looped or linear may be of any length. Typically the strand(s) would be long enough to allow the separated parts of the stent to be 2-4cm apart, although a length of separation of 1mm to more than 1m may be used.

In the circumstance where a longer length of strand(s) is used, whether looped or not, the strand may be bought directly to the outside of the body along the ureter, through the bladder and along the urethra. Here the stent would only consist of the upper curl which would be located in the renal collecting system e.g. the renal pelvis. When pressure transducers +/- electrodes are incorporated into the curl end of the stent in the kidney, the pressure measured in the renal pelvis may be directly conducted along wires as already described. When a transmitter is incorporated into the upper curl the pressure signal could be directly transmitted to a receiver/recorder on the outside of the body.

In addition when only the upper curl is used attached to a longer length of strand the curl may alternatively be placed in the bladder and the strand(s) pass from the bladder along the urethra to the outside of the body. In this circumstance pressure within the bladder alone could be measured.

The shape of the upper or lower ends does not have to be limited to a single curl. There may be more than one curl or different shapes to curls may be formed at the upper and lower ends. The aim is the same, that the shape formed by the stent at the upper and lower ends helps to keep the stent in position.

In addition although the stent is shown as a cylindrical tube, other shapes of tube are envisaged. For example the stent may have a ribbed or rippled surface, or may be solid, i.e. non-tubular, and may be of the same or similar diameter to the strand portion (see above). That is to say, the stent may be formed from a strand, or

strands, with a proximal retention portion and pressure sensors/electrical stimulators positioned strategically along its length. A distal retention portion may be incorporated as necessary.

It will be appreciated that this design allows for a good deal of flexibility. For example, the proximal end of the stent may be provided with a retaining means to keep the stent in the renal pelvis. A strand may then be attached to the distal portion and that strand may lead directly out of the patient along the ureter, through the bladder and along the urethra. Alternatively a middle section lying within the ureter may be incorporated if desired.

When there is a full stent, as shown in figure 3, the strand may pass from the lower or proximal curl along the urethra and out of the patient.

In a shortened stent the distal extension end portion may be adapted to fit into the bladder, in which case the kidney and ureter are unaffected.

Electrodes and/or pressure transducers may be located at any suitable points along the length of the stent.

While preferred embodiments of the invention have been illustrated and described, it is to be understood that the illustrations and descriptions are not meant as a limitation since further modifications may now suggest themselves to those skilled in the art and it is intended to cover such modifications as fall within the scope of the invention.

In summary, there is provided an indwelling ureteric catheter comprised of a flexible tube with an upper or distal end section, a substantially straight middle or intermediate section and a lower or proximal end section. These three sections may run in continuity or may be connected by at least one thin flexible strand. The upper end section is sited in use in the renal pelvis and the lower end section is located in use in the bladder.

The catheter may contain a number of electrodes and/or pressure sensors which can be present in any of the 3 main sections. These electrodes/transducers may be connected electrically via fine wires running along the catheter. When strands are

used to connect the sections with pressure transducers/electrodes in situ, the wires may pass along these strands. It will be appreciated that the electrodes and/or pressure transducers an be positioned anywhere along the length of the stent. It is not necessary that the electrodes/transducers have to be placed on a tubular portion of the stent. They could equally well be positioned along a strand portion or at a strand/tubular portion interface.

The catheter may also contain a battery supply and a telemetry system to transmit the recorded signals to the outside and provide electrical stimulation. Alternatively if the lower end is substantially straight and brought our transurethrally then the power supply can be external and the recordings from the transducers conducted externally rather than transmitted via telemetry.

CLAIMS

1. A ureteric stent having a proximal end and a distal end, said stent comprising:

(i) a proximal retention end portion positioned at the proximal end of the stent, said proximal retention end portion being adapted to retain said proximal portion in the renal pelvis of the patient;

(ii) at least one strand portion wherein said strand portion(s) has an outside diameter significantly less than the outside diameter of the proximal retention end portion;

characterised in that the strand portion(s) are located along the length of the stent such that, in use, the strand portion(s) are located across the pelviureteric junction and/or the vesicoureteric junction of the patient.

2. A ureteric stent as claimed in Claim 1 wherein the proximal retention end portion takes the form of a pre-formed coil.

3. A ureteric stent as claimed in Claim 1 or Claim 2 wherein the proximal retention end portion is formed form a tubular material having a hollow lumen.

4. A ureteric stent as claimed in any preceding claim wherein the distal end of said stent comprises a distal end retention portion adapted to retain said distal end in bladder of the patient.

5. A ureteric stent as claimed in Claim 4 wherein said distal end retention portion takes the form of a pre-formed coil.

6. A ureteric stent as claimed in Claim 4 or Claim 5 wherein the distal retention end portion is formed from a tubular material having a hollow lumen.

7. A ureteric stent as claimed in any preceding claim wherein said stent incorporates an intermediate portion, intermediate between the proximal end retention portion, if present, and the distal end retention portion, said intermediate portion being connected to adjacent portions by strands.

8. A ureteric stent as claimed in Claim 7 wherein said intermediate portion is formed from a tubular material having a hollow lumen.

9. A ureteric stent as claimed in any preceding claim further comprising one or more pressure transducers.

10. A ureteric stent as claimed in Claim 9 wherein one or more pressure transducers are positioned in one or more of the distal portion, the intermediate portion and/or the proximal portion of the stent.

11. A ureteric stent as claimed in Claim 9 or Claim 10 wherein signals from the pressure transducer(s) are transmitted from the stent via the strand portion(s).

12. A ureteric stent as claimed in any preceding claim wherein said stent further comprises stimulating electrodes.

13. A ureteric stent as claimed in Claim 12 wherein one or more electrodes are positioned in one or more of the distal portion, intermediate portion and/or the proximal portion of the stent.

14. A ureteric stent as claimed in Claim 13 wherein a stimulating electrode is positioned on the stent and a return electrode is positioned elsewhere on the patent's body.

15. A ureteric stent as claimed in Claim 12 or Claim 13 wherein a stimulating electrode and a return electrode are both positioned on the stent.

16. A ureteric stent as claimed in any preceding claim wherein a strand portion is secured to the adjacent portion of larger diameter by use of securing means.

17. A ureteric stent as claimed in Claim 16 wherein said securing means comprises one or more knots tied in the strand.

18. A ureteric stent as claimed in Claim 17 wherein the strand portion takes the form of a loop and is knotted to itself through the adjacent portion.

19. A ureteric stent as claimed in Claim 16 wherein said securing means comprises heat sealing.

20. A ureteric stent as claimed in Claim 16 wherein said securing means comprises crimping.

21. A ureteric stent as claimed in any preceding claim wherein said stent comprises a proximal retention portion and a strand portion, the strand portion being dimensioned such that it may be brought directly to the outside of the body along the ureter, through the bladder and along the urethra.

22. A ureteric stent as claimed in any preceding claim wherein the proximal retention end portion is adapted to retain said proximal portion in the bladder of the patent rather than in the renal pelvis.

23. A ureteric stent substantially as herein described with reference to and as illustrated in any combination of Figures 3 to 6 inclusive.

24. A method of measuring the pressure in the kidney and/or in the bladder comprising the steps of:-

(a) inserting into the patient a ureteric stent as claimed in any of Claims 1 to 23 inclusive, said stent incorporating one or more pressure transducers;

(b) measuring, and if necessary recording, the pressure in the kidney and the bladder.

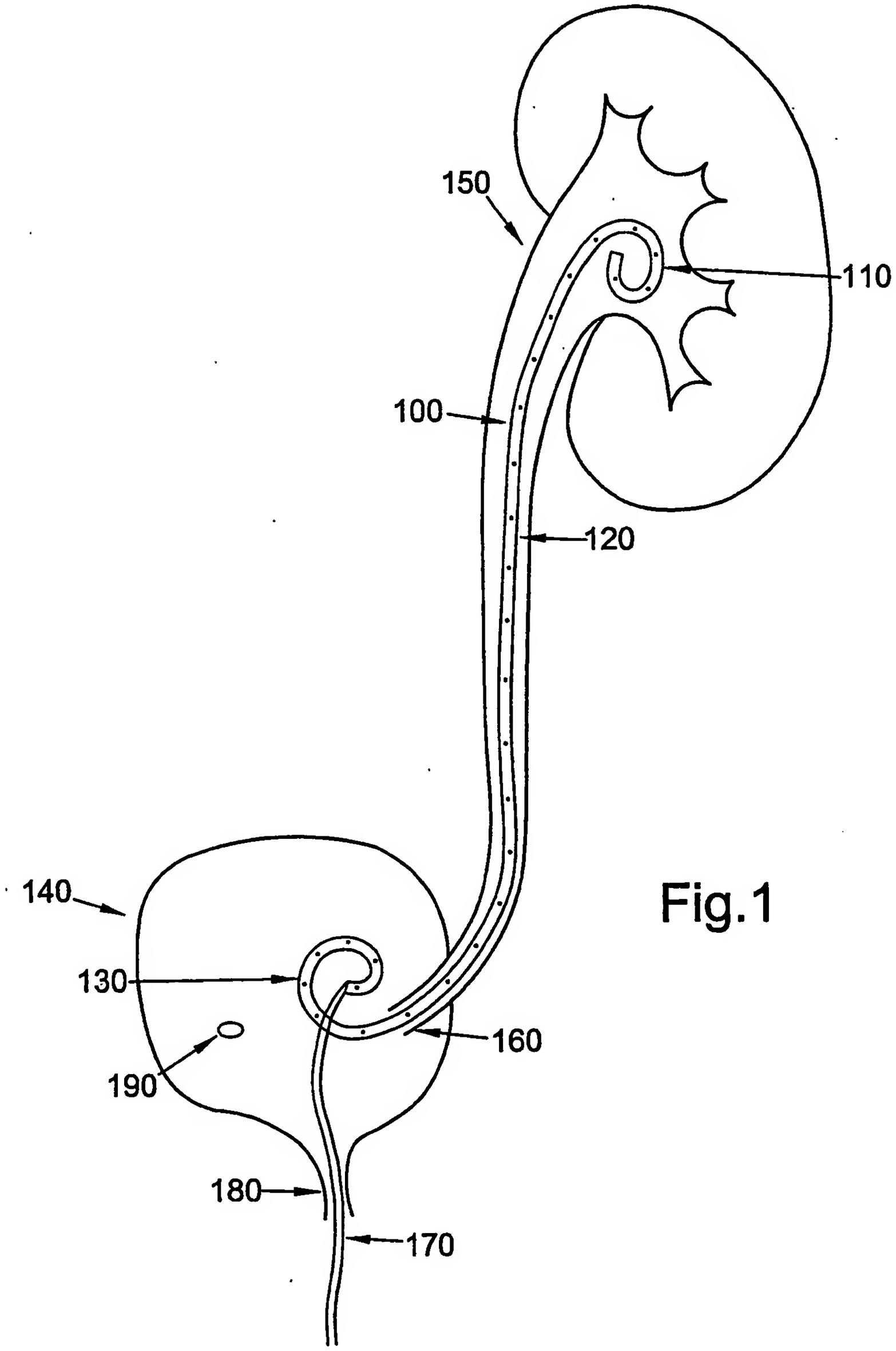

Fig.1

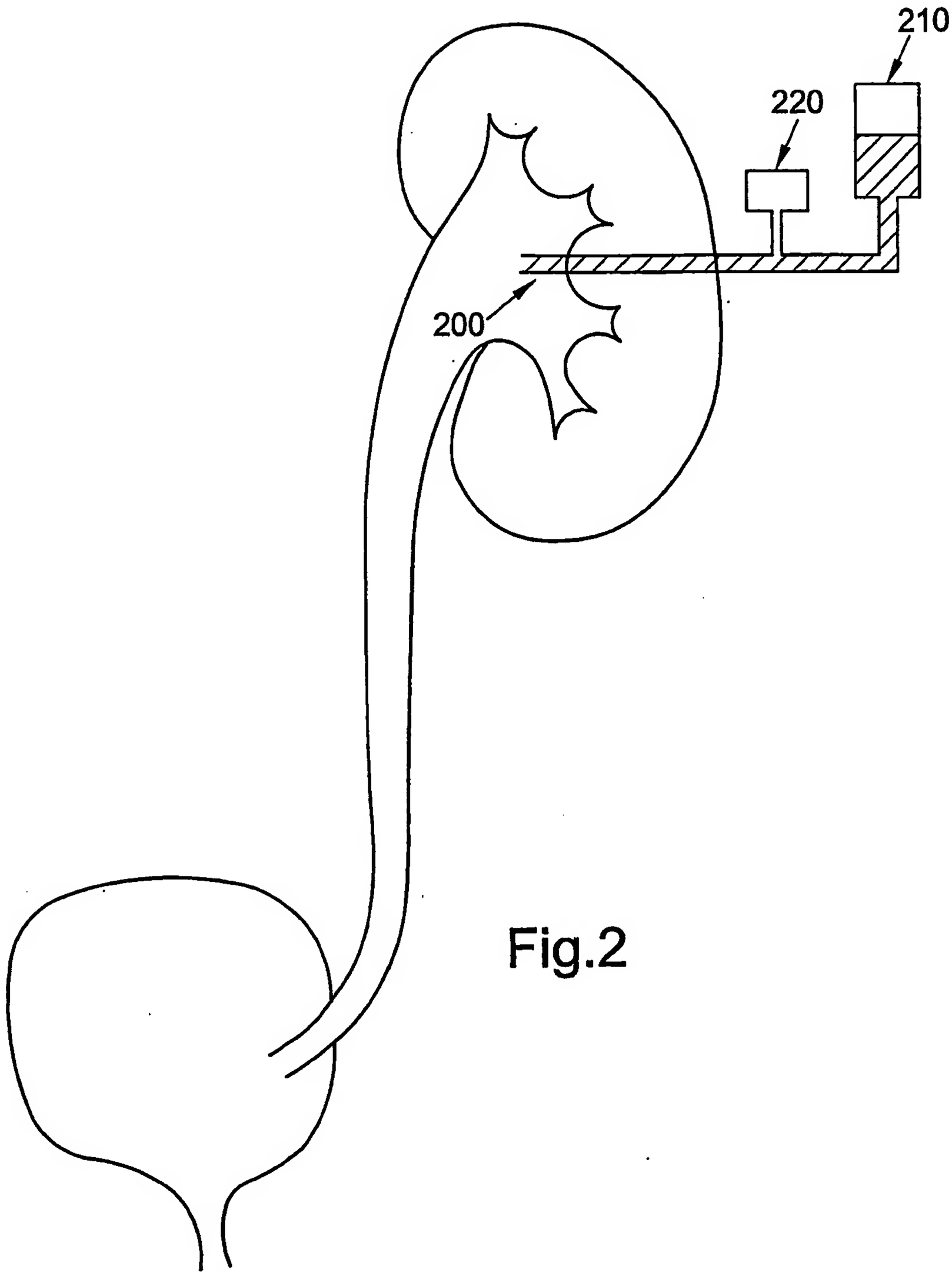

Fig.2

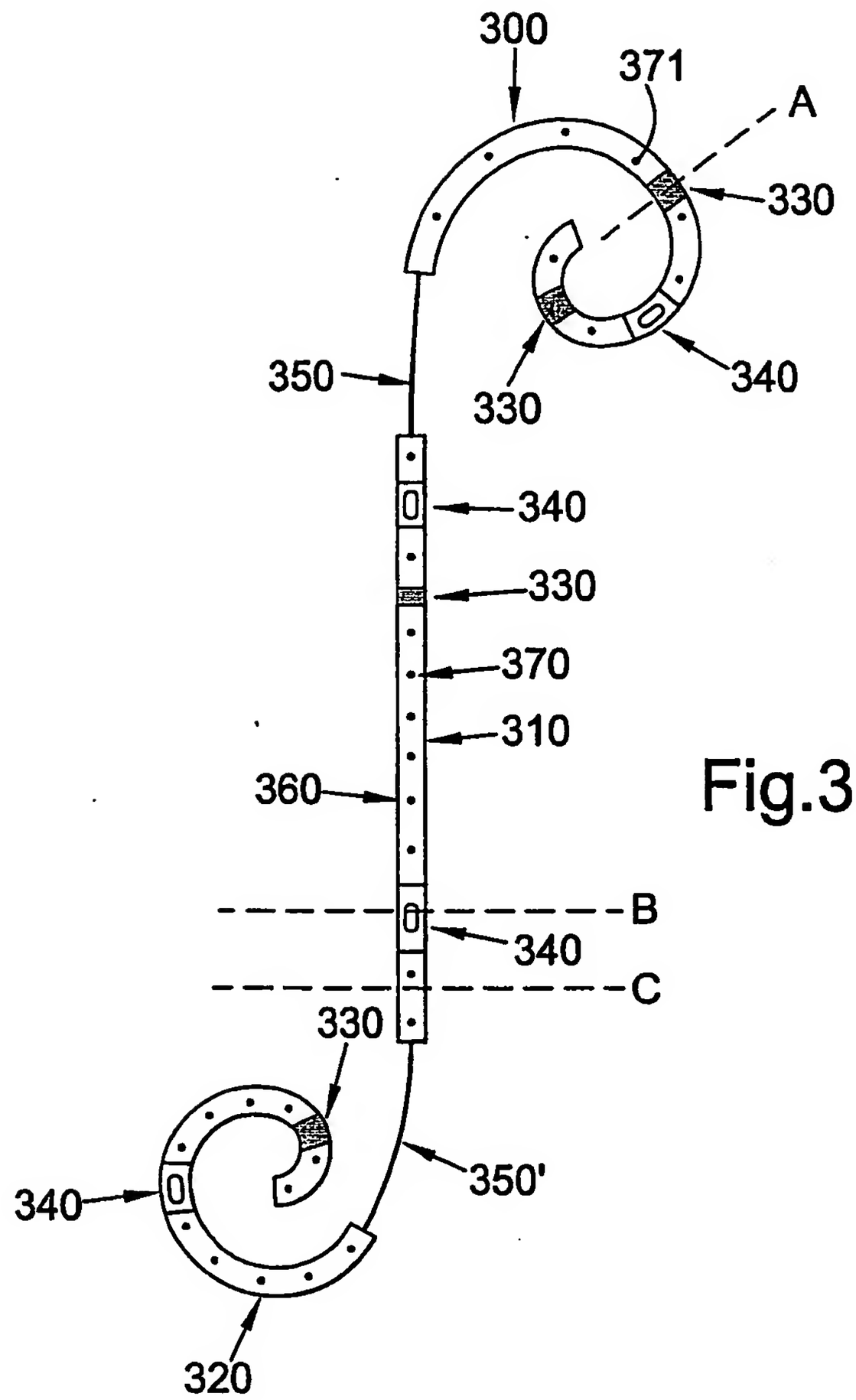
300
371
A
330
350
330
340
340
330
370
310
360
B
340
C
330
340
350'
320

Fig.3

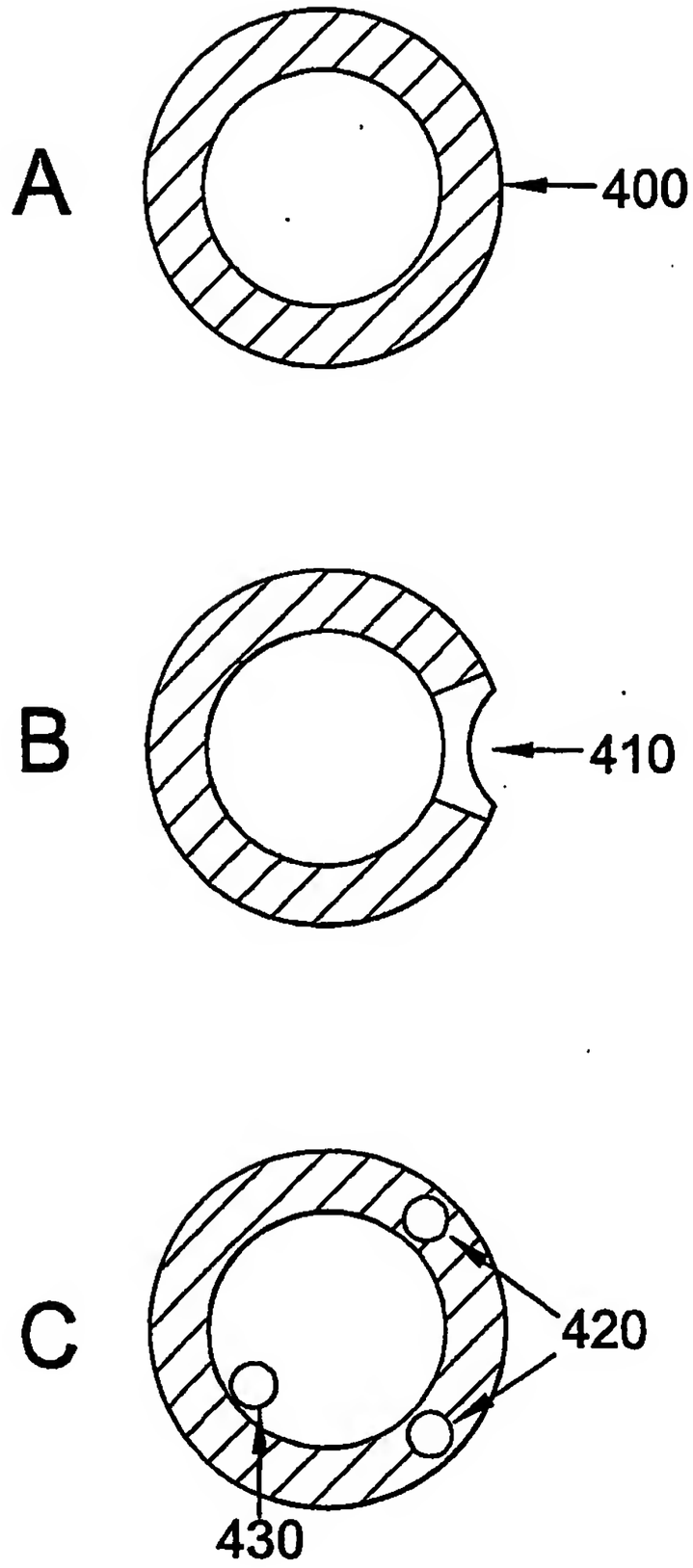

Fig.4

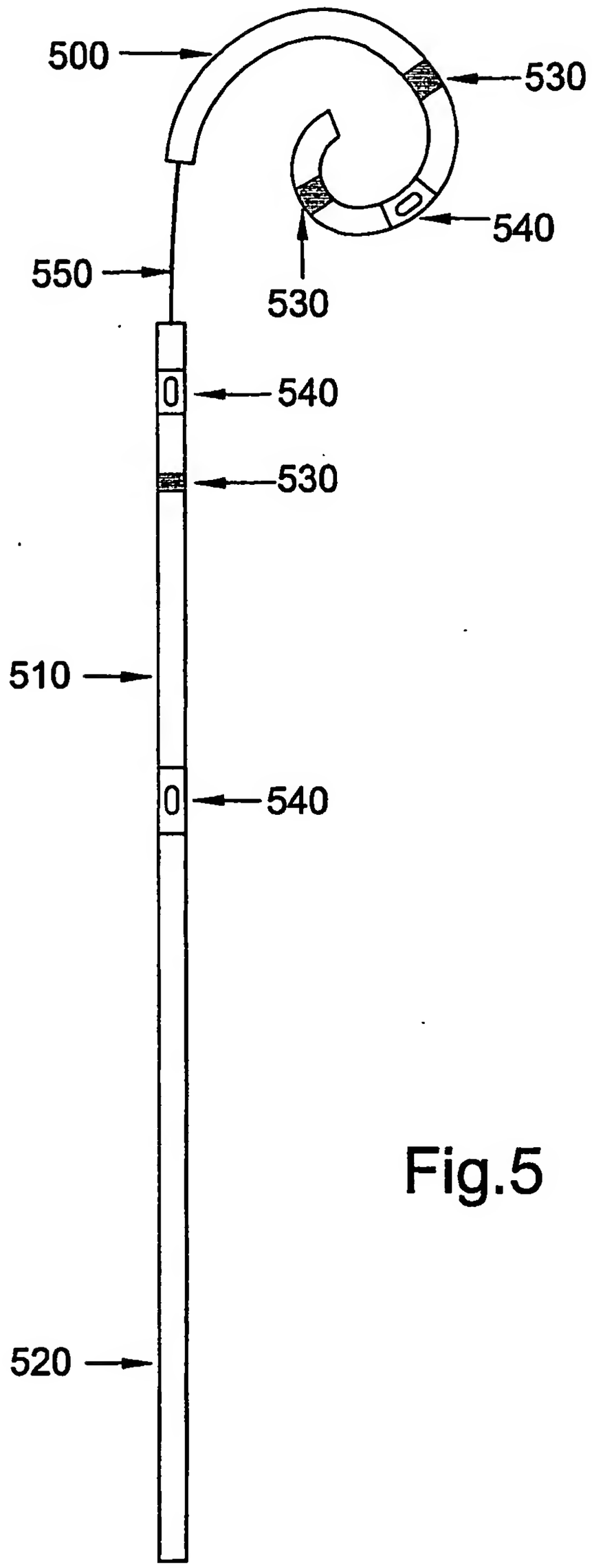

Fig.5

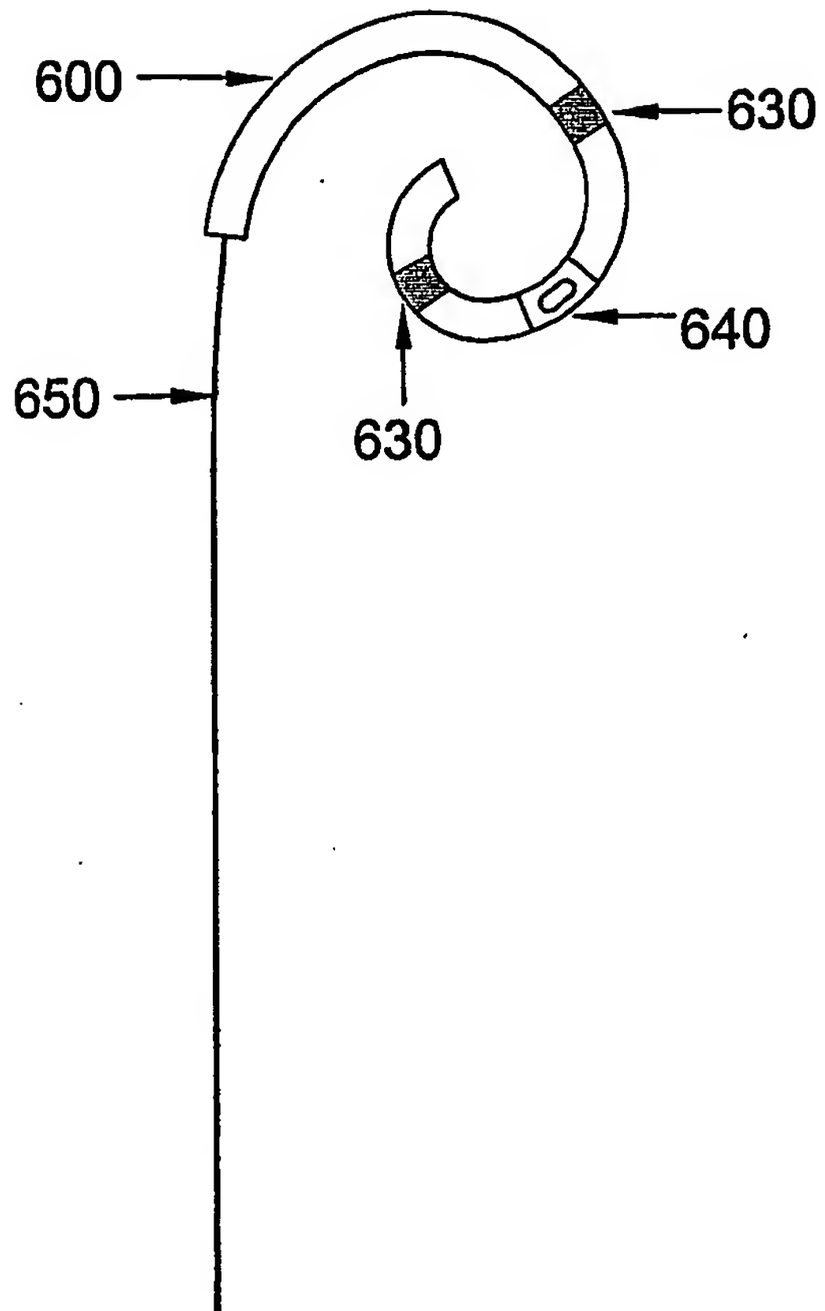

Fig.6

INTERNATIONAL SEARCH REPORT

GB2005/001348

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/04 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2003/109930 A1 (BLUNI SCOTT ET AL) 12 June 2003 (2003-06-12) figures 1a,2 paragraphs '0006! - '0008!	1-6, 17-23 7-16
Y	SU 1 412 774 A1 (KHARCHENKO VASILIJ M,SU) 30 July 1988 (1988-07-30) figure 5 & DATABASE WPI Derwent Publications Ltd., London, GB; AN 038519 abstract	7,8
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-/—

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 August 2005	16/09/2005
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax (+31–70) 340–3016	Authorized officer Franz, V

2

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

'GB2005/001348

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/181855 A1 (SIMPSON JOHN A ET AL) 25 September 2003 (2003-09-25) paragraph '0018!	13-16
X	US 6 656 146 B1 (CLAYMAN RALPH V ET AL) 2 December 2003 (2003-12-02)	1-3, 17-23
Y		9-16
A	column 5, line 55 - column 6, line 19 figure 8	4-8
X	US 6 332 892 B1 (DESMOND, III JOSEPH P ET AL) 25 December 2001 (2001-12-25) column 5, line 20 - line 36 figures 1a,3	1
X	WO 00/66032 A (APPLIED MEDICAL RESOURCES CORPORATION) 9 November 2000 (2000-11-09) figures 52,58,59	1
X	FR 2 661 603 A (CORALINES ABJ DIVISION SARL) 8 November 1991 (1991-11-08) figure 1	1
X	US 4 931 037 A (WETTERMAN ET AL) 5 June 1990 (1990-06-05) figure 1	1
A	EP 1 062 920 A (CONTICARE MEDICAL, INC) 27 December 2000 (2000-12-27) figure 2	1

2

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 24 25

Rule 39.1(iv) PCT - Claim 25 relates to a method for treatment of the human or animal body by surgery

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Continuation of Box II.2

Claims Nos.: 24

Present claim 24 relates to an extremely large number of possible apparatus. In fact, the claims contain so many options, variables, possible permutations and provisos that a lack of clarity (and conciseness) within the meaning of Article 6 PCT arises to such an extent as to render a meaningful search of the claims impossible.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

PCT/GB2005/001348

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 24 25
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Claim 25 relates to a method for treatment of the human or animal body by surgery

2. [X] Claims Nos.: 24
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

GB2005/001348

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